STATE OF HAWAII

REQUEST FOR EXEMPTION FROM CHAPTER 103F, HRS

To: Chief Procurement Officer

'05 JUL 11 P2:40

From: HEALTH/ Communicable Disease/ Tuberculosis Control
Department/Division/Agency

ADMINISTRATION
STATE PROCUREMENT OFFICE

Pursuant to § 103F-101(a)(4), HRS, and Chapter 3-141, HAR, the Department requests a procurement exemption to purchase the following:

Title and description of health and human service(s):
"Increasing Completion of Therapy for Tuberculosis Patients in Hawaii."
To strengthen directly observed therapy (DOT) services by augmenting coverage geographically & improving dosing time for patients. Contracted DOT services would be provided through non-traditional means such as a courier service, whose staff would be appropriately trained to deliver TB medication and observe its ingestion on a daily or other regularly scheduled basis. This is a year-long project to demonstrate the effective use of private services to accomplish the goals for completion of treatment set by the Centers for Disease Control in funding TB programs at the state level. This project also addresses the issue of decresed federal financial support, which has traditionally provided staff positions for DOT outreach workers.

Provider Name:	Total Contract Funds:	Term of Contract:
Courier Corporation of Hawaii	$27,500	From: July 1, 2005 To: Sept 30, 2006
Provider Address: P.O.B.30507,Honolulu, HI 96820	Contract Funds per Year (as applicable). As above	

Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State:
This request is for a temporary three-month exemption pending the issue of an RFP. The demonstration period for this award is one year only, beginning July 1, 2005. A temporary exemption is being sought to allow the most effective use of available funding over the entire period for which it is available. In order to demonstrate that a non-traditional, courier-type service can, with proper training, effectively provide DOT when budgetary and other concerns limit the program's ability to provide this sevice through regular staffing, other courier services have been contacted and have either not responded or have not shown interest in this project.

Details of the process or procedure to be followed in selecting the service provider to ensure maximum fair and open competition as practicable:
Other potential providers who have the ability to deliver the services as described by the Proposed Methodology section of the TB Program's application for funding to the American Lung Association (attached) have been contacted. The requirements of the grant have been stated & discussed with each potential provider. The provider selected meets these requirements by having the staff necessary to sustain adequate geographic coverage on a daily basis; the necessary skill level to perform DOT; and availability for proper training by TB Program staff prior to commencing their assignments.

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A description of the state agency's internal controls and approval requirements for the exempted procurement:
Initial contact with the service provider and details of the project were negotiated by the TB Program's Public Health Advisor (PHA) and approved by the TB Branch Chief. Discussions with subsequent potential providers were conducted by the TB Branch PHAO and approved by the Branch Chief.

A list of state agency personnel, by position title, who will be involved in the approval process and administration of the contract:
Jessie Wing, M.D., TB Branch Chief
Michael Zucker, TB PHAO

Direct questions to (name & position):	Phone number:	e-mail address:
Jessie Wing, M.D., TB Branch Chief	808-832-5737	jxwing@tb.health.state.hi.us

This exemption should be considered for list of exemptions attached to Chapter 3-141, HAR: Yes ☐ No ☒

I certify that the information provided above is to the best of my knowledge, true and correct.

Department Head Signature

JUL - 8 2005
Date

Chiyome Leinaala Fukino, M.D.
Typed Name

Director of Health
Position Title

Chief Procurement Officer's Comments:

Please ensure adherence to applicable administrative requirements.

☐ Approved ☐ Denied

Chief Procurement Officer *Date*

cc: Administrator
State Procurement Office

PEH No. 06-01

'Increasing Completion of Therapy for TB patients in Hawai`i'

Summary

Hawaii continues to report one of the highest annual state TB incidence rates in the United States with a case rate of 9.2 per 100,000 persons in 2004 (nearly twice the US national rate of 4.9/100,000). Because of our unique geography, immigration patterns, demographic and social history as a U.S. territory, Hawaii generally reports high TB rates among persons from Asia and the Pacific Basin (78% foreign-born TB cases in Hawaii in 2004). Over the past few years, there have been increases in single and multiple-drug resistant TB cases which can require a longer course of medications. Directly observed therapy (DOT) is the cornerstone of standard TB care to ensure completion of therapy (COT) for the six-nine month duration of medications for active TB cases. In addition, active cases managed by private physicians should have DOT offered as a standard of care, and preventive therapy should be offered to infected contacts and to other high-risk patients as directly observed preventive therapy (DOPT). However, the Hawaii TB Program has not been able to expand on these important core services due to staffing and funding restrictions in TB budget awards. Current staffing is stretched to cover the current DOT needs, and the potential impact from this process is a further increase in drug resistance and further complications for patient care in Hawai`i.

To improve DOT and COT, in this proposal, the Hawaii State Department of Health's Tuberculosis (TB) Control Program proposes to build on existing TB Clinic infrastructure and requests resources to fund additional staff dedicated to improving/expanding DOT and initiating DOPT services in Oahu, and increase funding for incentives and enablers for TB patients across Hawaii.

Background

The TB Program has adopted many of the CDC's objectives for care, including the following, as stated in the CDC Cooperative Agreement as listed below:

Current CDC TB Objectives:

National Objective 2: *At least 90% of newly diagnosed cases of tuberculosis will complete an American Thoracic Society/Centers for Disease Control (ATS/CDC) recommended regimen of anti tuberculosis therapy.*

National Objective 4: *At least 90% of the infected contacts under the age of 15 placed on preventive therapy, will complete a minimum of six continuous months of preventive therapy. At least 75% of infected contacts > 15 years of age placed on preventive therapy will complete a minimum of six continuous months of therapy.*

Standard CDC practices for Case Management and Completion of Therapy include maintaining dedicated staff to deliver Directly Observed Therapy (DOT, see other TB Definitions in Appendix 1) and utilize appropriate incentives and enablers to motivate and improve adherence to treatment plans that minimally last 6-9 months.

Over the past 5 years, the TB Program has witnessed a need to innovatively approach the challenges of delivering therapy and encouraging adherence for the duration of therapy. The CDC, American Thoracic Society, and the Infectious Disease Society of America currently recommend six months of therapy for active TB patients and 9 months for preventive therapy for patients with latent TB infection. If there is compromised drug adherence, complications in patient care and further drug resistance can result from stopping and re-starting medications.

At Lanakila Health Center, TB staff-DOT services have experienced diminishing returns due to problems in identifying and hiring outreach workers through normal state personnel processes. Additionally, personnel costs for DOT workers are high due to fringe and indirect costs since the DOT program is funded through the CDC cooperative agreement.

Appendix 2 has several tables and figures illustrating trend data from the Hawaii TB Program from 1999 to 2003. Table 1 shows the TB cases in the state, stratified by cohort type and analyzed by: cases who started medication (Rx), were on DOT, and had COT w/i 12 months. DOT is generally poor for cases managed by PMDs since self-administered medication is the norm. Though reported TB cases have decreased since 1999, only 62.8% (mean of 3 years data) received some form of DOT, leaving 37.2% on some form of self-administered therapy that is not recommended by CDC. For COT w/in 12 months, we did not achieve an important CDC goal of 90% completion of therapy.

Table 2 illustrates COPT data among high risk patients (infected contacts to active TB cases) and shows poor outcome with only 41% COPT in 2003. There has been little DOPT of high-risk patients (infected contacts) thus far.

The two figures illustrate data on drug resistant (DR) cases which showed a significant increase in 2002. DR (both single and multi-drug resistant) cases are generally more complicated: they are more labor intensive (requiring more nursing/physician visits), more expensive requiring second line bacterial-static medications, and require more DOT hours to follow until COT (extended to 12-24 months of therapy). In 2003 there were more multidrug-resistant TB cases than usually reported (3.4% vs the ~1.2% reported nationally). Note there are no data on DOPT or baseline data on use of incentives and enablers (since these have been offered for several years).

In order to reverse the general downward trend in TB Treatment completion, particularly treatment completed within 12 months, the Hawai`i TB Program is requesting funding from ALA-Hawai`i for two specific interventions intended to increase the rate of treatment completion for TB and LTBI patients in Hawai`i.

The Hawaii TB Program Goals for this proposal are to:

- **Increase DOT services to private sector patients and other high risk patients**

- **Begin directly observed preventive therapy (DOPT) to high risk patients in Oahu, including infected contacts to active TB cases to increase COPT**
- **Improve Completion of Therapy (COT) through increased funding for incentives and enablers for patients**

The Hawaii Department of Health Tuberculosis Control Program requests funding to build on the infrastructure of the TB program and purchase additional goods and services to implement the following two interventions:

1- **Improve DOT services by increasing staff to improve coverage geographically and improve dosing times for patients.**

2- **Increase funding for incentives and enablers to encourage completion of treatment (COT)**

Total Request: $ 119,200

Proposed methodology:

I. Improve DOT services by increasing staff to improve coverage geographically and improve dosing times for patients.

Several factors have impacted TB clinic services in the past five years, including a major clinic renovation from 2002-2003 (clinics were in temporary quarters and services disrupted), a new Nurse Supervisor (supervisor of OWs), a new pharmacist (new policy that effectively shifted DOT medication work load to Nurses/OWs), other retirements and difficulty filling positions in the State.

Reliable family members may occasionally provide DOT services in some particular cases though DOH staff provided DOT is preferred. TB patients managed solely by private medical doctors (PMDs) often have self-administered medications (SA, no DOT). Co-managed cases (variable definition based on responsibilities shared between TB Program and PMD) have decreased since the senior TB physician retired in March 2004, leaving only 1 other TB physician who participates in co-management. OWs are still assigned to geographic districts in order to cover the entire Island of Oahu (eg, the low population density North Shore must be included even though there may only be 1 TB patient located in that district). Though 2004 data have not been closed or fully analyzed, we suspect that data trends will be worse for DOT/COT.

From the early 1990's, the Hawaii TB Control Program has employed as many as 7 Outreach Workers (OWs) with federal funds to provide DOT services in Oahu. The TB Program has recently experienced attrition of 5 OWs (due to sickness and retirement). Despite two rounds of interviews since late 2004, only one candidate has been identified but has not yet commenced employment as a new OW. Currently the program has only 2

full-time OWs. These 2 OWs, along with Public Health Nurses, and 1-2 part-time recently hired staff provide DOT for the entire island of Oahu. This will become more difficult in Summer 2005 when the PHNs will not be able to provide DOT due to increased clinic volume.

Funding from the Hawaii State has been effectively reduced in 2005, which further compromises the ability to cover current level of services and expand services for private DOT and DOPT patients. Federal funds that support OWs has been static for the past 5 years and will likely decrease next year due to a new funding initiative by the CDC based on the number of TB cases reported and other CDC goals.

Our plan to augment DOT service provision in Hawaii addresses several issues, which are currently difficult to address by State staff. Although our clients have 24-hour lives, we are restricted to business hours to efficiently deliver DOT. Also, we must bear the costs of owning and maintaining cars for DOT staff to use. By contracting an external agency to manage DOT, more people can be served at expanded hours, potentially including weekends. This does not replace current TB staff; currently very few private patients receive DOT and there are no patients receiving Directly Observed Preventive Therapy in Oahu even though CDC objectives recommend it for patients who are at high risk of developing TB disease. *Any* referred patient (whether public or privately managed) could then receive DOT (or DOPT) from the contractor, expanding both the scope and reach of TB services.

State policies for procurement of such services by an external agency would require that this be offered to the public in the form of an RFP and a bid process to award such a contract. Additionally, if the State TB Program administers such a contract directly, there is a possibility that the process could be challenged by the Union due to concerns about current state staffing procedures.

The TB Program plans to work with the contractor to provide overall monitoring and management or co-management of the TB patient in this new process. We also hope to finally fill the TB Physician vacancy and resume (and perhaps increase the proportion of) co-management of TB cases with the private sector (which appears to increase the DOT uptake).

One option in providing care with an external agency is described below (see Appendix 3, Budget details):

5 days per week DOT

- Cost per worker $70.00 /day (4hrs)
- Vehicle and Overhead Cost $70.00/day
- Daily cost per worker $140.00

- Weekly cost per worker $700.00
- Cost per year: $36,400

- 3 workers: *$109,200 for Yr 1*

This arrangement is a departure from conventional practices in TB programs across the country. In most cases, mileage would be specified in an agreement to perform field services. In this case, mileage is not indicated specifically because these numbers were developed by a commercial enterprise interested in piloting this program cooperatively with DOH and a third party with technical advice from the TB Branch. This enterprise has a fixed daily accounting cost for the vehicles, which is an average vehicle cost across their enterprise. This is a statewide company with many vehicles and the amount expressed distributes the cost of maintenance and fuel across the whole enterprise, representing a cost savings over maintaining single vehicles and paying individual mileage totals. Because we are not dealing with individuals, the cost is aggregated and the overhead cost stated includes insurance, vehicle costs, fuel costs and administrative costs associated with managing personnel and a fleet of vehicles.

In the private sector, physicians are required by law to submit a notifiable disease report to the TB Program when active TB is first suspected. Additionally, labs must submit positive TB smear and/or culture information to the Program. This allows a signal after which the program can contact the physician and offer DOT services to the private patient.

II. Increase patient incentives and enablers for completion of therapy and completion of preventive therapy (COT/COPT)

Incentives and enablers (IEs) have long been an accepted mainstay of standard CDC TB Case Management to encourage and assure compliance with care plans and adherence to therapy. The 2005 CDC grant provides for $5000 for IEs to encourage DOT and COT. State purchasing limits, the State purchase order process, and the need to purchase from price lists restricts the most effective application of incentives and enablers by making it difficult to tailor incentives and enablers to individual patients. The Hawaii TB Program seeks to improve patient adherence to care plans and medication by broadening the array of incentives for TB patients. Many patients initiate therapy but drop out after the first 2 –3 months of the 9 month regimen; adherence is key to COPT. On the Neighbor Islands (Hawaii, in particular), the high price of gasoline and infrequent bus service makes gas cards a valuable incentive (and enabler) for some patients.

In addition, the TB program supports TB Prevention by supplying medicine and expertise to local health care providers through the Community TB Prevention program. By offering incentives to these providers for their TB Prevention patients, greater completion rates for preventive therapy and higher potential to prevent cases of TB can be expected.

Because of price list and purchasing restrictions, the TB Program requests that ALA purchase incentives and enablers such as listed below. See budget details in Appendix 3.

1. **Incentives for active TB Cases to complete therapy**

- Broaden current spectrum to include incentives, such as:

1. Fast Food Gift Certificates
2. Gift Cards for Bookstores
3. Movie Tickets
    a. Adults (pair)
    b. Kids /seniors (pair)
4. Movie/Game Rentals
    a. Blockbuster Gift Cards
5. Overseas Phone Cards
    a. To call Philippines/Asia
6. Pre-paid gas cards

2. **Offer to high risk pts to improve Completion of Preventive Therapy (COPT)**

- Offer to encourage completion of preventive therapy

1. Movie Tickets
    a. Adults (pair)
    b. Kids/Seniors (pair)
2. Overseas Phone Cards

- Offer to maintain adherence during 9 mo of therapy

1. Fast Food Gift Certificates
2. Foodland (or Sack 'n Save) Gift Certificates
3. Pre-paid gas cards

Total for Year One **$119,200**

Monitoring and Reports
Monitoring of this grant will be done to track the use of incentives and enablers. Per HIPPA standards (and other concerns for patient privacy), the PHN will be asked to record variables such as:

- date
- clinic name (Lanakila HC or other)
- clinic # of the patient who received the IE
- type of patient (active TB Class 3 or LTBI Class 2)

- type of incentive/enabler used
- PHN initials, etc.

A paper-based spreadsheet (or an Excel or Access database can be developed) to track and aggregate data for reporting every 6 months to ALA-H. For DOT/DOPT, the contractor will be required to note the date, the patient serviced, medication delivered, any side effects/problems/or questions asked by the patient, etc and provide these data to the TB Program in a timely manner.

Indicators of Success

The TB Program hopes to demonstrate improvement in several key areas with the innovative approaches described above. However, other factors in the Program's infrastructure (state hiring practices, funding, union issues) may also ultimately affect the final outcomes. We aim to have:

- A higher proportion of the public *and private* patients with active TB in Hawaii covered by DOT services
- For the first time, high risk patients with latent tuberculosis infection (LTBI) can be offered DOPT
- Completion rates for preventive therapy (COPT) will increase
- High risk infected cases will receive program-supported incentives as well as medication to enhance completion of therapy and prevention of TB cases

More specifically, our current targets for 3 years (with 2003 baselines) subject to availability of funds:

DOT goals:

Cohort	2003	Year 1	Year 2	Year 3
Public only	**94.9%**	95%	96%	97%
Private MD only	**0.0%**	25%	50%	55%
Co-managed	**96.2%**	96%	97%	98%

COT w/in 12 month goals:

Cohort	2003	Year 1	Year 2	Year 3
Public only	**76.3%**	78%	82%	84%
Private MD only	**76.9%**	78%	80%	82%
Co-managed	**82.0%**	86%	88%	90%

DOPT/COPT goals:

Cohort	2003	Year 1	Year 2	Year 3
% DOPT	0	25%	40%	45%
% infected contacts started on Rx	59.7%	65%	72%	75%
% COPT of infected contacts	41.0%	48%	52%	55%

These goals may appear somewhat conservative, however success may depend on several factors, including: the training period required for the workers, ramping up of services to full capacity, seasonality of TB cases matched to staffing levels (summer generally busier than spring), immigration patterns, morbidity of TB patient (infectiousness, presence of drug resistance, HIV status, homelessness), the number of contacts, proportion of extended families (can increase the complexity of finding contacts and decrease COPT), general funding/stable infrastructure of the program to maintain other staffing/services, etc.

Total funding request:

	Year 1
I. DOT services	109,200
II. Incentives/enablers	10,000
	$119,200
Total request	

It is hoped that at end of yr 1, the results consider second yr of funding.

Appendices:

1- Some TB Definitions
2- Data tables, figures, Hawaii 1999-2003.
3- Budget details
4- References

Appendix 1.

Some TB Definitions

- **Active TB patient: patient with diagnosis of *Mycobacterium tuberculosis***
  - Directly observed therapy (DOT) of active TB patients
  - Completion of Therapy (COT) of active TB patients

- **LTBI: latent TB infection**
  - Directly observed preventive therapy (DOPT) in patients with latent TB infection
  - Completion of preventive therapy (COPT) in patients with latent TB infection

Appendix 4:

References

American Thoracic Society and Centers for Disease Control and Prevention. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. Am J Respir Crit Care Med. Vol 161, ppS221-S247, 2000.

American Thoracic Society and Centers for Disease Control and Prevention. Diagnostic Standards and Classification of Tuberculosis in Adults and Children. Am J Respir Crit Care Med. Vol 161, pp 1376-1395, 2000. Hopewell PC. (Editorial) Targeting tuberculosis prevention. Am J Respir Crit Care Med. Dec 2000.

American Thoracic Society, Centers for Disease Control and Prevention, Infectious Diseases Society of America: Treatment of Tuberculosis. Am J Respir Crit Care Med 2003; 167: 603-662.

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Core Curriculum on Tuberculosis. What the Clinician Should Know. Fourth edition, Centers for Disease Control and Prevention, 2000. Accessed at: http://www.cdc.gov/nchstp/tb/pubs/corecurr/default.htm Dec 2002.

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